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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,806	04/26/2001	Brian Anthony Whittle	65,213-001	9829

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,806

Applicant(s)

WHITTLE, BRIAN ANTHONY

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Priority

1. The applicant's claim for priority under 35 U.S.C. 365(c) is acknowledged. Receipt is acknowledged of papers submitted under this statute, which have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Takaichi *et al.* (WIPO Document No. WO 96/22704)

The Takaichi *et al.* document discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the composition (See Abstract; Page 2, Line 12 to Page 3, Line 22). The amount of calcium oxide to be included in the composition is not to exceed 1.0 % by weight (See Page 4, Lines 10-21). A sour agent is also to be used and may be an organic acid, including citric acid and ascorbic acid (See Page 6, Lines 11-15). Other components, such as binders, excipients, and disintegrators may also be included, and the

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composition may be prepared using methods already known in the art (See Page 6, Line 16 to Page 7, Line 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilen.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Wilen patent teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (See Example 2). Although the precise amount of magnesium sulfate is left to be determined by one of ordinary skill in the art, based on the disclosure of a previous example (See Example 1), it would be obvious that magnesium sulfate would be present in a quantity less than 10% by weight of the composition.

4. Claims 1, 2, 4, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.*

The Takaichi *et al.* document discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the composition (See Abstract; Page 2, Line 12 to Page 3, Line 22). The amount of calcium oxide to be included in the composition is not to exceed 1.0 % by weight (See Page 4, Lines 10-21). A sour agent is also to be used and may be an organic acid, including citric acid and ascorbic acid (See Page 6, Lines 11-15). Other components, such as binders, excipients, and disintegrators may also be included, and the composition may be prepared using methods already known in the art (See Page 6, Line 16 to Page 7, Line 5).

5. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.* in view of Wilen, Needleman *et al.* (U.S. Patent No. 5,993,854), Theeuwes (U.S. Patent No. 4,036,228), and Buysch *et al.* (U.S. Patent No. 5,502,232)

The Takaichi *et al.* document discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the composition (See Abstract; Page 2, Line 12 to Page 3, Line 22). The amount of calcium oxide to be included in the composition is not to exceed 1.0 % by weight (See Page 4, Lines 10-21). A sour agent is also to be used and may be an organic acid, including citric acid and ascorbic acid (See Page 6, Lines 11-15). Other

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components, such as binders, excipients, and disintegrators may also be included, and the composition may be prepared using methods already known in the art (See Page 6, Line 16 to Page 7, Line 5).

The Takaichi *et al.* patent does not teach a composition comprising magnesium sulfate, either as the sole anhydrous compound, or in combination with calcium oxide, with either compound not exceeding 10% by weight of the composition. The patent also does not teach a composition that further comprises an acid or acid salt and a carbonate or bicarbonate in an effervescent composition. The patent does not teach a composition that further comprises a sulfite or calcium lactate.

The Wilen patent teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (See Example 2). Although the precise amount of magnesium sulfate is left to be determined by one of ordinary skill in the art, based on the disclosure of a previous example (See Example 1), it would be obvious that magnesium sulfate would be present in a quantity less than 10% by weight of the composition.

The Needleman *et al.* patent teaches an effervescent composition (See Abstract). The effervescent agent in the composition comprises an alkaline carbonate salt, which may be chosen from a group comprising sodium bicarbonate, sodium carbonate, potassium bicarbonate, potassium carbonate, magnesium carbonate, calcium carbonate, and combinations thereof (See Column 2, Lines 24-41). The effervescent agent further comprises an acid, which may be chosen from a group comprising tartaric acid, maleic acid, lactic acid, citric acid, ascorbic acid, sodium sulfite, potassium sulfite, and combinations thereof (See Column 2, Lines 42-61). The

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composition further comprises an exothermic agent, which may be chosen from a list that includes calcium oxide and magnesium sulfate (See Column 3, Lines 3-20). Furthermore, Needleman *et al.* disclose a problem known in the prior art of the moisture sensitivity of effervescing ingredients, and the need to avoid contact with even ambient humidity in order to preserve the shelf life of an effervescing product (See Column 1, Lines 36-50).

The Theeuwes patent teaches an osmotic device that dispenses a drug by the use of a gas-generating means (See Abstract). The gas-generating means preferably comprises a solid acid component and a solid basic component. Among the acids that may be used is malic, tartaric, maleic, and citric acid. Alternately, their corresponding anhydrides may be used as well. The solid basic component is preferably includes the carbonates and bicarbonates of alkali metals and alkali earth metals and mixtures thereof (See Column 4, Line 60 to Column 5, Line 36). The patent also mentions the use of a water scavenging process to control the acid-base reaction of the effervescing action (See Column 5, Lines 37-50). An osmotically effective compound may also be included in the composition to aid in the effervescing action. Such compounds include magnesium sulfate, sodium carbonate, sodium sulfite, calcium bicarbonate, and calcium lactate; mixtures of these compounds may also be used (See Column 7, Lines 1-30).

The Buysch *et al.* patent is relied upon as a teaching reference that acknowledges the dessicating properties of calcium oxide and magnesium sulfate in the prior art (See Column 5, Lines 14-38).

It would be obvious to one of ordinary skill in the art to combine the teachings of Takaichi *et al.*, Wilen, Needleman *et al.*, Theeuwes, and Buysch *et al.* into the object of the instant application. Wilen, Needleman *et al.*, and Buysch *et al.* all teach various effervescent

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compositions. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), “It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill would be motivated to combine these three references in order to gain a more complete understanding of the substances that may be included in an effervescing composition. Based on the disclosure in *Needleman et al.* regarding the moisture sensitivity of effervescing compounds, one of ordinary skill would be motivated to combine the teachings *Takaichi et al.* and *Buysch et al.* with the combined teachings of *Wilen*, *Needleman et al.*, and *Buysch et al.* in order to formulate a composition that prevents interaction of water with the effervescing components of said composition, improving stability and shelf life. Thus, the invention as a whole is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
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sjo
July 24, 2002

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